Testimony by
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I testify today as one who has been a patient in a hospital and as a consultant in the field of pharmacy automation.

Twenty-seven years ago Wrigely's put a barcode on a pack of chewing gum. This really was a statement of faith as grocery and drug stores did not have scanners. But, their faith was not in vain. For within a decade, virtually every item on the shelves of drug stores and super markets had a barcode. And the vast majority of checkout stands were equipped with scanners to read them.

Within five years (1990) virtually every retail item had a barcode—not just Q-Tips at Walgreens and Cheerios at Safeway, but also duct take Home Depot and dresses at Nordstrom.

Barcodes on everything. Scanners everywhere. Almost.

Not until 1991 was the first "unit-dose" medication bar-coded by a manufacturer. Today, ten years later, two thirds of all medication packages still show up at bedside without barcodes. And, less than 3% of our hospitals have scanners at the point of medication administration.

The reason: For years the drug manufacturer's argued, why should we apply barcodes if hospitals don't have scanners. And hospitals argued why should we buy scanners when drugs don't have barcodes.

It's like a slapstick comedy with a couple of keystone cop cars at a narrow bridge, not crossing because the drivers are shouting back and forth, "After you, no after you."

FDA, please help us get across this bridge.

We request that you require that labels on all medications contain machine–readable codes so we can scan (or auto-read) them at the point of medication administration.

There are numerous safety benefits that barcodes and scanning can bring to the medication Distribution and Dispensing process. But even more importantly they promote safety at the Point of Administration.

Verification: We are able to scan the barcode on a patient wrist band and up comes profile of drugs due. Next we select and scan the barcode on each drug item to verify that this is the correct drug for this patient at this time.

Documentation: Too often nurses proceed as if the M in MAR (medication administration record) stands for Memory. They come to the end of a shift and fill out the MAR the way we will fill out expense accounts on the heals of this meeting. What day was this taxicab receipt for? What time did I give that medication to patient Jones? Or was it Smith? Did I even give it after all?

The result: we end up with an *approximate* MAR. Safe monitoring and prescribing are built on Accurate MARs. I certainly do not want my physician adjusting any drug therapy I'm on based on a estimated MAR.

Which symbology do we want on these labels?

Answer: *Today's machine-readable codes, which today's scanners can read.*

We hope you will avoid the symbology wars. Today's barcode readers are smart enough to read multiple symbologies. Simply require that the symbologies utilized be open-architecture and that that they have been standardized via a recognized standards organization.

Let the market decide which symbology(s) will prevail to standard.

What exactly is it that we want to be bar-coded?

Unfortunately, the nomenclature among us who advocate barcode labeling has been a bit ambiguous. Some say barcode down to the unit-of-use, others say to the unit-dose. Do we all mean the same thing by these terms? Obviously not.

I personally argue it is a misnomer to call a manufacturer blister or syringe, for example, a unit dose.

Manufacturers determine the unit of measure they will pack, but they don't determine doses. Physicians in consultation with pharmacists determine doses.

The true unit-dose might be two tablets of a mfg 5mg in a blister "unit-dose" package. Or 2ml of a mfg 4ml "unit-dose" syringe.

Our confusion in terms has not helped us in getting across the barcode packaging and scanning bridge.

I think we can get through the confusion if we simply use FDA nomenclature on this one. Current FDA regulations related to drug labeling do not use the terms "unit-dose" or "unit-of-use,", but rather refer to immediate containers.

Immediate containers include blisters and bottles for pills, ampoules, vials and syringes and bags for liquids, tubes and canisters for salves, etc.

We want the labels on all immediate containers to include barcodes.

What information should this barcode contain?

Currently, the FDA requires all immediate containers be labeled, *in human readable print* with Drug/Strength/Mfg…as well as Lot Number and Expiration Date.

I am suggesting that the machine-readable code needs to contain the same information the FDA already in human readable print.

While it would be ideal to have all these data required immediately, we are willing to have you stage implementation if necessary. Immediately require Drug/Strength/Mfg. As soon as possible require the addition of Lot No & Expiration Date

I assume that the FDA feels compliance with drug recalls and pulling expired meds are important. The accreditation bodies and state boards sure do.

While it is possible for caregivers to utilize human readable expiration dates and respond accordingly, it is virtually impossible for a caregiver to identify an outdate by a human readable number, as the human readable number without a reference point is meaningless.

It is incredibly labor- and time-intensive for the pharmacy personnel to comb through the inventory scattered throughout the pharmacy and hospital and actually outdates, even when they have a reference to the number. It's like hunting for a needle in a haystack.

Embedding these data sets in the barcode of the immediate container would solve this problem by preventing the caregiver from administering an outdated medication.

Act Quickly

With or without the manufacture packaging support, Hospitals have begun navigating their way across the bedside scanning bridge. This makes your prompt action all the more important. VA hospitals are scanning all administrations by mandate. Other hospitals have joined them and many others are getting ready to roll. The fact is, each of these hospitals is becoming a labeling house by default. And none are carrying out this labeling in a manner that comes close to GMPs, as manufacturers and packaging houses must.

The efficacy of bedside scanning, to which hospitals are careening, stands or falls on the integrity of the packaging. We simply cannot rely on pharmacists or technicians manually applying barcodes to ampoules, vials and syringes, as I witnessed a volunteer doing in one VA hospital.

In conclusion:

Bedside Scanning is to Patient Safety what wearing seatbelts is to passenger safety. It's not the only thing, but it is a salient thing. We still have to drive sober, defensively, have good tires and breaks. Likewise, we still have to diagnose properly and prescribe and dispense accurately, But when everything is said and done scanning, like seatbelts saves lives.

Please require drug manufacturers to apply machine-readable codes to all immediate containers of medication, embedded with Drug, Strength, Mfg, Lot Number and Expiration Date.

In so doing, you will help eliminate the “after you,” ‘No, after you” exchange between hospitals and drug companies. Help us get across this bridge.

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